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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,316	08/22/2001	Ching-Leou Teng	ISIS-4824	1463
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COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			EXAMINER ANGELL, JON E	
			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/935,316

### Applicant(s)

TENG ET AL.

### Examiner

J. Eric Angell

### Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Action is in response to the communication filed on 11/5/03. The amendment has been entered. Claims 1-15 have been cancelled. Claims 16-27 are pending in the application and are examined herein.

### ***Election/Restrictions***

2. Applicant's election with traverse of group II (claims 16-27) and the species: capric acid and polyacrylic polymers, is acknowledged. The traversal is on the ground(s) that the additional search required for group I would not constitute a serious search burden. This is not found persuasive because, as indicated in the previous Action, the search required for Group I is not co-extensive with the search required for group II. For instance, the search for group II would require searching form methods of using the product in a subject, while this search would not be required for group I. The searches are not co-extensive which is indicative of a serious search burden.

The requirement is still deemed proper and is therefore made FINAL. Claims 16-27 are examined herein.

### ***Specification***

3. The abstract of the disclosure is objected to because the use of the trademarks (for example, Carbopol 934 NF and Methocel E4M; see, e.g., p. 52 and claims) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26 and 27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26 and 27 contains the trademark/trade name Carbopol 934 NF and Methocel E4M, respectively. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe bioadhesives and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,877,309 (McKay et al.).

8. The instant claims are drawn to:

A method for enhancing the intestinal absorption of a drug in an animal, comprising orally administering to said animal an oral formulation, comprising:

(a) a first population of carrier particles comprising said drug and a bioadhesive compound; and

(b) a second population of carrier particles comprising a penetration enhancer (claim 16);

wherein the animal can be a mammal (claim 17) or a human (claim 18); wherein the carrier particles may be administered separately or together (claims 19 and 20); wherein the drug is an oligonucleotide (claims 21); wherein the penetration enhancer is the fatty acid capric acid (claim 22); wherein the bioadhesive is a polyacrylic polymer (claim 23); and wherein the oligonucleotide is an antisense oligonucleotide (claim 24).

McKay teaches a method which comprises administering to a human a composition comprising an antisense oligonucleotides as a drug, wherein the antisense oligonucleotide is comprised in a formulation which can comprise capric acid and polyacrylates (e.g., see: col. 20,

lines 52-54, column 6, lines 29-65; col.22, lines 4-19; col. 23, lines 24-40; col. 25, lines 1-7; and col. 28, lines 3-4).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 16, 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,877,309 (McKay et al.), further in view of US Patent 5,514,788 (Bennett et al.).

It is noted that McKay teaches a method for enhancing the intestinal absorption of a drug in an animal, comprising orally administering to said animal an oral formulation, comprising: (a) a first population of carrier particles comprising said drug and a bioadhesive compound; and (b) a second population of carrier particles comprising a penetration enhancer (claim 16); wherein

the drug is an oligonucleotide (claims 21), and specifically where the drug is an antisense oligonucleotide, as previously indicated.

McKay does not teach that the oligonucleotide has SEQ ID NO: 1 (claim 24).

However, Bennett teaches an antisense oligonucleotide that exactly matches SEQ ID NO: 1 of the instant claims (see SEQ ID NO: 22 in column 35 of Bennett) wherein the antisense oligonucleotide is contemplated for use in a method where it is administered to an animal (e.g., see abstract).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by McKay such that the antisense oligonucleotide described by Bennett (which is SEQ ID NO: 1) was the oligonucleotide drug used in the method, with a reasonable expectation of success.

The motivation to make the modification is provide in part by both McKay and Bennett. Specifically, McKay teaches a method for orally administering any therapeutic oligonucleotide to an animal and Bennett teaches a specific antisense oligonucleotide (that has SEQ ID NO: 1) is a therapeutic antisense oligonucleotide that can be administered to animals.

### ***Conclusion***

No claim is allowed.

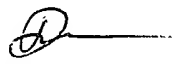
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell, Ph.D.  
Art Unit 1635

  
DAVE T. NGUYEN  
PRIMARY EXAMINER